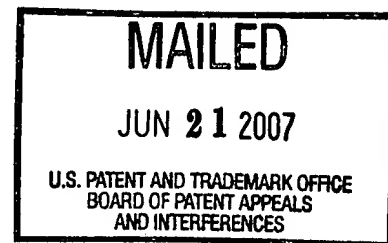


1 RECORD OF ORAL HEARING
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3 UNITED STATES PATENT AND TRADEMARK OFFICE
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6 BEFORE THE BOARD OF PATENT APPEALS
7 AND INTERFERENCES
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10 *Ex parte* TOMMY EKSTROM
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13 Appeal 2007-1154
14 Application 09/367,950
15 Technology Center 1600
16



17
18 Oral Hearing Held: May 17, 2007
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22 Before TONI R. SCHEINER, DONALD E. ADAMS, and
23 RICHARD M. LEOVITZ, Administrative Patent Judges
24

25
26 ON BEHALF OF THE APPELLANT:

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33 The above-entitled matter came on for hearing on Thursday,
34 May 17, 2007, commencing at 11:15 a.m., at the U.S. Patent and Trademark
35 Office, 600 Dulany Street, Alexandria, Virginia, before Lanieda D. Briggs,
36 CSR No. 10571, Notary Public.

1 THE CLERK: Calendar number 36, Mrs. Fraser.

2 JUDGE SCHEINER: Good morning, Mrs. Fraser. Sorry we're
3 running so behind. Take whatever time you need to get ready and then
4 you'll have 20 minutes.

5 MS. FRASER: This is actually my first oral hearing, so you'll
6 have to prompt me on the procedures here.

7 JUDGE SCHEINER: There really isn't much. You just tell us
8 your position on the rejections and we'll ask you questions, maybe. We may
9 or may not depending. And of course you are confined to what's in the brief.

10 MS. FRASER: Okay. Thank you.

11 JUDGE ADAMS: And if you could, spend some time on claim
12 13 just defining what that claim is giving us, a claim construction on claim
13 13. That would be really helpful.

14 MS. FRASER: There are a number of independent claims.
15 That isn't the only one. But I will focus on that one if you like. They are
16 fairly similar. Okay.

17 Claim 13 and all of the claims, really, relate to methods of
18 preventing and treating asthma symptoms. And in each case the claim is
19 written in terms of instructing a patient to inhale an effective amount of a
20 composition that comprises an admixture --

21 JUDGE ADAMS: Wait. "Instructing a patient," that's the same
22 as, like, a product insert, some instruction that goes with this inhaler? That's
23 what you are talking about?

24 MS. FRASER: That would be one embodiment.

1 JUDGE ADAMS: So instructing a patient would be like a
2 written description, printed matter, printed matter along with this inhaler,
3 like a kit that comes with instructions?

4 MS. FRASER: It could be. We're not claiming the kit here.

5 JUDGE ADAMS: I understand.

6 MS. FRASER: And it wouldn't have to be written instructions.
7 It could be the physician speaking to the patient. It could be, you know, a
8 video that the physician hands to the patient, any way of communicating
9 these instructions.

10 It's to inhale this effective amount of a composition that
11 contains two ingredients, one of which is the known Beta-agonist formoterol
12 (phonetic) and the other which is the known steroid, Budesonide.

13 JUDGE ADAMS: If I could stop you there. The prior art
14 Carling teaches an inhalant that has these components.

15 MS. FRASER: Yes, it does. And then importantly, this
16 method is characterized in that the patient is instructed to inhale the
17 composition on demand, determined by the patient based on the patient's
18 symptoms as both the treatment and a preventative measure when the patient
19 experiences asthma symptoms.

20 JUDGE ADAMS: That's the real big issue in this case -- is this
21 on demand, quote, unquote.

22 MS. FRASER: That's the big issue with respect to the
23 obviousness part.

24 JUDGE ADAMS: Okay. What does that mean? Could that
25 include two or less times a day?

1 MS. FRASER: In this particular claim there is no requirement
2 that there be additionally a maintenance therapy, but some of the claims do
3 require maintenance therapy, and that's once or twice a day every day. This
4 claim specifies just the on-demand part, which could mean zero times a day.

5 JUDGE ADAMS: Or it could mean the maintenance two times
6 a day.

7 MS. FRASER: It could end up being no more than two times a
8 day.

9 JUDGE ADAMS: So you have an overlapping patient
10 population with Carling, right?

11 MS. FRASER: The patient population is not the criteria here,
12 it's what instructions are given to the patient, and here the patient is told,
13 Take this when you need it, is essentially what that claim says.

14 JUDGE ADAMS: So if I understand you correctly, it's this
15 printed matter that you say is critical to this particular claim. That's the only
16 thing that distinguishes this claim from Carling, the printed matter of the
17 product insert?

18 MS. FRASER: The content of the -- we're not claiming printed
19 matter. It's not a composition -- yes, it's not a composition claim or a kit
20 claim or an article manufacture, it's a method.

21 So it's the content of the instructions that is different from what
22 Carling teaches. If you like, I could go right into the obviousness first, but I
23 would definitely like to be able to address the enablement rejection issue as
24 well.

1 Carling, as you pointed out, does teach the same, an inhaler
2 containing exactly the same composition, these two precise ingredients.
3 Carling however teaches delivery just as a maintenance therapy twice a day,
4 and I'll point you to where in Carling. Do you have Carling in front of you?

5 JUDGE SCHEINER: Yes.

6 JUDGE ADAMS: Yes.

7 MS. FRASER: It teaches it in a few places, but let's focus on
8 page 6 starting at line 22.

9 The intended dose regimen is a twice-daily administration
10 where the suitable daily dose of formoterol is blah, and the suitable daily
11 dose for Budesonide is blah, with the preferred dose of blah, and then it goes
12 on to say, The particular dose used will strongly depend on the patient age,
13 weight, et cetera, and the severity of the disease, mild, moderate, severe, et
14 cetera.

15 You can see from the beginning of that paragraph that Carling
16 is focused on what is essentially maintenance therapy twice a day with
17 administration. This is consistent with how the art knew to use a steroid,
18 which is Budesonide, which is an antiinflammatory.

19 It is not a short-acting dilator by any means. It's a slow-acting
20 drug and it's used to prevent the symptoms of asthma long term so the
21 patient will take it regularly. That will, one hopes, keeps down the level of
22 inflammation. It's slow-acting and it's not ever meant to be used as a
23 bronchodilator.

1 JUDGE ADAMS: Carling says it could be the maintenance
2 administration or it could be used once in the day, once at night. What does
3 he say about instructing the patient?

4 MS. FRASER: Nothing as far as I can tell.

5 JUDGE ADAMS: But one reading Carling would appreciate
6 this dosage, maintenance dosage for this particular type of inhaler because of
7 the formulation. So you would expect that due to the product insert -- or the
8 physician would say, You take this thing twice a day. In fact, that's what
9 you are arguing in your brief, right?

10 MS. FRASER: That's right.

11 JUDGE ADAMS: So that gets us back to this claim
12 interpretation. Carling would, while it doesn't expressly say it would, one
13 would reasonably expect the product insert or the physician would instruct
14 the patient to use Carling's inhaler once or twice a day maintenance therapy.

15 So really the only difference between your quote, claim 13, in
16 Carling is on demand. As I mentioned to you earlier, on demand, and you
17 agree, could be maintenance therapy, so what's the difference between your
18 claim and Carling?

19 MS. FRASER: On demand wouldn't be maintenance therapy.
20 Maintenance would be the physician telling the patient, Take it twice a day,
21 no more, no less. I don't care how you feel.

22 JUDGE ADAMS: You agree that there probably will be a
23 patient population that will only need this and will only see on demand as
24 twice a day.

1 MS. FRASER: But it would be up to the patient every day to
2 decide that. If the patient feels that his or her symptoms warrant taking it
3 right now, the patient would take it right now. If the patient didn't feel it
4 warranted it, they wouldn't. The instruction to the patient would be different
5 whether it was intended as a maintenance therapy or on demand.

6 The Carling inhaler was actually ultimately marketed, is on the
7 market currently, and the product insert for that is part of the exhibits that we
8 supplied with our brief. If you would like to take a look at that, we can do
9 so to see how the art actually uses the Carling inhaler at this point.

10 That would be Exhibit B with our --

11 JUDGE LEBOVITZ: But what kind of limitation is instructing
12 a patient? I mean, this isn't -- there is no administration required by the
13 claim, correct?

14 MS. FRASER: That's right.

15 JUDGE LEBOVITZ: So no administration. So this all turns on
16 whether instructing a patient to take on demand, I think -- if it's not taught by
17 the prior art. Let's take that scenario. It's not taught by the prior art. The
18 prior art teaches maintenance dose taking it twice a day no matter what, no
19 demand. Is that a patentable limitation, instructing a patient?

20 MS. FRASER: It's certainly not within the types of --

21 JUDGE LEBOVITZ: It's not a process. It's not a composition
22 of matter.

23 MS. FRASER: It's a method. It's a method of instructing a
24 patient.

25 JUDGE LEBOVITZ: Is that like a business method?

1 MS. FRASER: I'm not an expert on business methods, so I
2 don't know whether if it technically would be characterized as that. It's a
3 method like a method of doing anything.

4 JUDGE LEBOVITZ: You can actually patent the doctor telling
5 -- handing a known medication to a patient and saying, Take this on
6 demand? That's what you are trying to patent here?

7 MS. FRASER: Yes, and there is no prohibition in the U.S. law
8 for -- doctors can be infringers under U.S. law. It's not an issue and there is
9 no limitation. The Supreme Court has said that certain categories of things
10 are not patentable, and I don't believe instructing patients is one of those
11 categories that isn't patentable. It's everything under the sun is patentable.

12 JUDGE LEBOVITZ: Anything manmade under the sun.
13 Human-made, let's say.

14 MS. FRASER: I would say instructing a patient is something
15 that's manmade. It's certainly not a phenomenon of nature.

16 JUDGE SCHEINER: I'm troubled by the fact that this doesn't
17 actually require -- this is a method that does not actually require any
18 manipulative steps other than instructions which could be printed, verbal,
19 mimed.

20 MS. FRASER: I think it would have to be communicated,
21 though, not just written and hidden in a vault somewhere. There is an act of
22 communication.

23 JUDGE SCHEINER: Right. I understand that this is couched
24 as a method claim, but I'm wondering how relevant the case is, the
25 composition case is that talks about written instructions.

1 MS. FRASER: Like In re Ngai. Do you know how to
2 pronounce that?

3 JUDGE SCHEINER: I don't know how to pronounce it either.

4 MS. FRASER: I'm glad you brought that up. That is, as you
5 say, it's a written instruction. It has to do with an article manufacturer, a kit
6 in that case where there were written instructions.

7 JUDGE SCHEINER: Clearly, it's not exactly on point but
8 somehow it's relevant.

9 MS. FRASER: I thought through that question, because I
10 actually thought it might come up, and I think -- I don't believe there are any
11 cases on point having to do with a method claim.

12 JUDGE SCHEINER: I'm not aware of one.

13 MS. FRASER: And there is very little analysis in that In re
14 Ngai case. It was written as a non-precedential opinion and then changed to
15 a precedential opinion without further elaboration, so it is very conclusory.
16 There isn't a lot to hang your hat on to understand how the case would go
17 with the method claim, but they did focus on the teachings in another case in
18 the Gulack case.

19 The In re Ngai, the court depended, relied on some language in
20 that case. That had to do with the printed matter being on a band, and it was
21 said to be patentable because the printed matter was interrelated. The
22 function of the printed matter interrelated with this circular band, and there
23 was -- so they said an inner-relationship.

1 JUDGE SCHEINER: It had to have -- the printed matter had to
2 be in a certain physical position in order to -- it wasn't just the content of the
3 printed matter. It was its physical position on the bands.

4 MS. FRASER: That's right, and the two acted together.

5 JUDGE SCHEINER: Which gave it a functional --

6 MS. FRASER: That's right. So similarly, the act of
7 communicating -- let's say a physician is talking to the patient here, and so
8 the act of communicating is interrelated with the content of what's being
9 communicated.

10 So the instruction here, the content of the instruction that forms
11 the basis for this claim is certainly interrelated with the act of advising or
12 instructing a patient. You can't separate the two. And so in that way it's
13 similar to the Gulack case.

14 JUDGE SCHEINER: But suppose that it has no need of the
15 drug, though. Suppose it never results in the patient taking the drug, or
16 suppose it results in the patient taking the drug twice a day. And this is an
17 asthma patient and Carling describes self-administration of this drug twice a
18 day.

19 So in the situation where the patient finds the need to take this
20 twice a day, the patient is the same as Carling's patient and the manipulative
21 steps would be the same, so we're saying somehow the patient's
22 understanding of the instructions makes it patentable over Carling.

23 MS. FRASER: It's the conduit of what's communicated.

24 JUDGE SCHEINER: I'm troubled by this.

25 MS. FRASER: It's not what the patient understands.

1 JUDGE SCHEINER: It's what's communicated to the patient.

2 MS. FRASER: It's what instructions are given by the
3 instructor.

4 JUDGE SCHEINER: So the only manipulative step is someone
5 somehow giving the patient instructions and we don't care what happens
6 after that?

7 MS. FRASER: That's right. What happens after that is not an
8 element of the claim.

9 JUDGE LEOVITZ: Are you familiar with Lungren, which is
10 a board case, which is a precedential case on, I think, the technological arts
11 test or rejecting that whether it was a case -- it comes from the old line of
12 cases -- it addresses one of the old line of cases where you have to have a
13 tangible, concrete result, what Judge Scheiner was talking about, no
14 manipulative steps here, so it doesn't require you to take it at any time.

15 All it does is require an instruction. So the question is, you
16 know, is this really the kind of subject matter that the patent office considers
17 patentable? And there should have been several board cases recently which
18 address that. Did that come up on the radar at all during the prosecution or
19 were you thinking about the claim?

20 MS. FRASER: No, in fact, this issue has not been raised at all
21 during prosecution.

22 JUDGE ADAMS: If I could take you off on a tangent here just
23 so I can help define what your intention is with this claim.

24 Everywhere we see the claim say, Instructing a patient to
25 inhale, why don't we read that as administering?

1 Now, if we read the claim, the claimed method as a method that
2 comprises administering an effective amount of a composition comprising
3 these two ingredients characterized in that the patient is administered the
4 composition on demand, would you say, then, that it encompasses the
5 patient population that is the same as or that is also encompassed by
6 Carling?

7 MS. FRASER: That would be quite a different claim than the
8 one I'm considering here or the one that's before us. Because it would be
9 something the patient would be doing, you self-administer the drug. It isn't
10 something somebody gives to you, so we would look at the patient as being
11 the infringer.

12 And the patient -- and if it just said the patient takes it twice a
13 day, then that would be the same as Carling. But taking it on demand would
14 imply that you take it when -- well, it's not just on demand. It says, "As
15 determined by the patient."

16 JUDGE ADAMS: The patient administers this composition to -
17 - let's use himself -- on demand. Then this patient, this particular patient
18 population only needs maintenance therapy?

19 MS. FRASER: Then it --

20 JUDGE ADAMS: Twice a day, boom, boom. That's Carling.

21 MS. FRASER: Maintenance therapy is something you don't do
22 based on symptoms. You do it if you are feeling great. You do it if you are
23 feeling terrible. It has nothing to do with your symptoms. Whereas, on
24 demand is modulated to what your symptoms are.

1 JUDGE ADAMS: Okay. So that gets us down to the last
2 clause when the patient experiences an increase in asthma symptoms. Does
3 that mean -- let me ask you instead of trying to interpret it. Let me ask you,
4 how do you interpret that last clause?

5 MS. FRASER: The patient would -- let me read through it,
6 make sure I get it right.

7 JUDGE ADAMS: Please.

8 (Pause in proceedings.)

9 MS. FRASER: Okay. The patient is told to inhale the
10 composition as determined by the patient based on when the patient
11 experiences an increase in asthma symptoms.

12 So the instruction would be, Here's an inhaler. You decide
13 when to take it, and the way you decide when to take it is if you feel an
14 increase in your asthma symptoms, take it. If you don't feel an increase in
15 your asthma symptoms, you know, this instruction doesn't apply.

16 JUDGE ADAMS: Okay. Now, let me back off of this, what
17 you tell a patient. It's going to say, Patient administers this -- let's not get
18 into all of this fuzzy stuff right now -- characterized in that the patient
19 administers the composition when the patient experiences an increase in
20 asthma symptoms?

21 MS. FRASER: Yes.

22 JUDGE ADAMS: What is it -- an increase in asthma
23 symptoms, you suggested was something more than the twice-a-day
24 maintenance therapy that's contemplated by Carling?

25 MS. FRASER: It's something different from that, yes.

1 JUDGE ADAMS: Why.

2 MS. FRASER: Why?

3 JUDGE ADAMS: Yes.

4 MS. FRASER: Because the maintenance therapy you take
5 twice a day every single day regardless of your symptoms.

6 JUDGE ADAMS: Why wouldn't this claim read on the -- we're
7 going to use administration. Why wouldn't this claim read on administering
8 twice a day?

9 MS. FRASER: It would, only if those twice a day were linked
10 specifically to asthma symptoms.

11 JUDGE ADAMS: Is that a reasonable -- that connection,
12 maintenance therapy versus increase in asthma symptoms, is that a
13 reasonable connection?

14 MS. FRASER: No, maintenance therapy you take regardless of
15 how you feel and you don't take additional ones even if you are feeling
16 terrible.

17 JUDGE ADAMS: Carling says, Take this particular
18 formulation as an inhaler for maintenance therapy twice a day.

19 MS. FRASER: Yes.

20 JUDGE ADAMS: Your claim says, Take this same
21 formulation and take it when you experience it -- experience an increase in
22 asthma symptoms, which theoretically means something more than
23 maintenance therapy.

24 MS. FRASER: Something different than.

25 JUDGE ADAMS: Does your specification tweak that out?

1 MS. FRASER: Well, yes, we --

2 JUDGE ADAMS: Point me to it.

3 (Pause in proceedings.)

4 MS. FRASER: Okay. The first -- well -- relevant is the first
5 sentence under the summary of invention on page 2. A suitable composition
6 for manufacture predicament for treatment of acute episodes of asthma as a
7 complement to maintenance therapy.

8 JUDGE LEOVITZ: What page is that?

9 MS. FRASER: Sorry, page 2, the middle of the page.

10 The next paragraph talks about using the composition for
11 symptomatic relief. On page 3, I'm not sure exactly what you are looking
12 for here. I'm just sort of wandering through the spec.

13 JUDGE ADAMS: To be more clear, why it would be your
14 position that your claim reads on inhaling or dosing more than twice a day
15 which would be known or recognized in the art as a maintenance regime?

16 So along the lines of, you know, like, the first section you
17 pointed to under the summary of invention, if the use is suitable composition
18 for the treatment of asthma as a complement to maintenance therapy.

19 Maintenance therapy, as I understand what I've read here, is
20 twice a day, typically with whatever inhaler you are using. It's twice a day
21 with these particular steroid formulations, right.

22 MS. FRASER: That's right.

23 JUDGE ADAMS: Now, the question is, when we drop all the
24 way down, we get to the last clause of your claim 13. You are talking about

1 a patient that experiences an increase in asthma symptoms, that's when this
2 patient will take more than this maintenance therapy.

3 So the question is, what is it in your specifications that supports
4 you are not just inhaling this stuff for maintenance therapy; you are inhaling
5 this composition for more than just the maintenance therapy?

6 MS. FRASER: Okay. Well, the sentence that I pointed to as a
7 complement to maintenance therapy.

8 In addition to that, the paragraph in the middle of page 3 that
9 begins at line 9, "It lies within the scope of the present invention to use the
10 compositions comprising active compounds A and B for treating acute
11 conditions of asthma and intermittent asthma episodes, chronic asthma, in
12 addition to treating chronic asthma on a regular basis with the same
13 compound."

14 JUDGE ADAMS: So this in addition to treating chronic
15 asthma would be the maintenance dose?

16 MS. FRASER: Yes. The next sentence is preventative use,
17 "When the patient expects to encounter," so it would be at that point. When
18 you expect to encounter those, you take it.

19 JUDGE ADAMS: That was the two-line paragraph following
20 the one?

21 MS. FRASER: That's right.

22 JUDGE ADAMS: It's basically on and on and on with that
23 general concept, right?

24 MS. FRASER: That's right. The idea -- the concept behind it is
25 really fairly remarkable. The Budesonide, of course, is a known -- long-

1 known steroid, been used for a long time for maintenance therapy. As
2 indicated in the evidence that we submitted with our brief, it was always
3 done as a twice a day, sometimes once a day, but never more than twice a
4 day, and very rigidly applied.

5 The physician would instruct the patient according to the
6 materials that were packaged with the Budesonide with the prior art, the
7 physician would say take it twice a day, absolutely no more.

8 If you miss one of your treatments, don't take an additional
9 dose. Just go back to the -- into the regular cycle. Don't take an additional
10 dose and don't ever take more if you are feeling worse. Don't ever take less
11 if you are feeling great. Just take the two doses.

12 The reason was because it would give no benefit to the patient
13 or thought to be of no benefit to the patient in an acute attack. It's very slow-
14 acting. It's not a bronchodilator. If you have an acute attack, you need a
15 bronchodilator.

16 Budesonide is a steroid and potentially dangerous to overdose,
17 so that's why the instructions are always very strict about not taking more
18 than the set maintenance dose.

19 JUDGE ADAMS: Okay. So let's go back and take a look at
20 claim 13. We went through the specification and you showed me what
21 appears to be various places where you are taking this particular formulation
22 as an inhaler for more than a maintenance dose, right?

23 MS. FRASER: Yes.

24 JUDGE ADAMS: That's what's intended by claim 13; is that
25 right?

1 MS. FRASER: Claim 13 doesn't mention maintenance dosing.
2 It could be done by a patient who is not taking any maintenance doses.
3 There are other claims that specify both maintenance and maintenance
4 dosing and the additional.

5 JUDGE ADAMS: Maintenance dosing is twice a day, right,
6 typically?

7 MS. FRASER: Yes, typically.

8 JUDGE ADAMS: And claim 35, for example, it's basically the
9 same claim as 13 except the last clause of that claim says, As a complement
10 to maintenance therapy?

11 MS. FRASER: That's right.

12 JUDGE ADAMS: That reads on something that's more than
13 twice a day?

14 MS. FRASER: Yes.

15 JUDGE ADAMS: Claim 13 does not?

16 MS. FRASER: Claim 13 would permit one or two or --

17 JUDGE ADAMS: It could, but claim 13 reads on maintenance
18 therapy.

19 MS. FRASER: No, I wouldn't -- I mean, the instruction is not
20 to do maintenance therapy. The instruction in claim 13 is to take it on
21 demand, and the patient would be taking it when the symptoms require it,
22 and in maintenance therapy you don't take it when symptoms require it. You
23 take it a set time twice a day.

24 JUDGE ADAMS: So then it really does come down to the last
25 clause in claim 13?

1 MS. FRASER: The on-demand part as determined by the
2 patient based on the patient's symptoms. It also comes down as a treatment
3 and preventative measure, and it's the entire clause, not just that very last
4 part.

5 JUDGE ADAMS: Okay.

6 JUDGE SCHEINER: It's a very interesting case.

7 MS. FRASER: There is a lot of interesting issues. So the
8 examiner -- would you like to ask another question or should I proceed?

9 JUDGE ADAMS: I'm good for the moment.

10 JUDGE SCHEINER: I don't have anything further.

11 JUDGE ADAMS: Is there anything else you wanted to say
12 about the 103 rejection?

13 MS. FRASER: Yes. The examiner took that paragraph that I
14 read to you out of Carling. That was on page 6, the one that began with the
15 intended regimen dose as twice daily administration and focused on the last
16 sentence.

17 The particular dose used will strongly depend on the patient's
18 age, weight, et cetera, and the severity of the disease, asthma, et cetera. And
19 the examiner took that to mean since the particular dose is based in part on
20 severity, then it must be up to the patient to decide when to take patient --
21 when to take doses.

22 So the examiner ignored the twice-daily part that was at the
23 beginning of that sentence and decided the patient should decide when the
24 patient's age and weight requires a different dose and when the patient's
25 severity of disease required a different dose.

1 JUDGE SCHEINER: So your position is it's really the amount
2 that's referred to at the end there, not the time?

3 MS. FRASER: That's right. The amount that the physician
4 says to take as the maintenance therapy. It would be entirely decided by the
5 physician, and the art would have understood that.

6 So in the Supreme Court KSR case, they emphasized common
7 sense as being a criterion for putting together a motivation for making the
8 claimed invention. To me, it's not common sense to interpret that as being a
9 direction to the patient to decide for himself or herself how much to take in a
10 given day. That wouldn't be consistent with the art and it's not consistent
11 with common sense.

12 JUDGE ADAMS: You back that up with a product insert that's
13 basically -- got you.

14 MS. FRASER: Good.

15 JUDGE ADAMS: Anything else on the 103 before we move
16 on?

17 MS. FRASER: Pointing out, but I don't want to go into the
18 details. There is strong evidence of teaching away based on the art on those
19 product inserts on how the art knew to use Budesonide and other steroids.
20 We have very strong teaching away and fabulous surprising results that you
21 just couldn't ask for better surprising results in a case.

22 JUDGE ADAMS: The result, quote, surprising results, where
23 you could use this thing more than twice a day; is that right?

24 MS. FRASER: Not just use it, but get much better results, far
25 better than you would have gotten if you were taking it twice a day and the

1 patient were using a normal short-acting inhaler for the breakthrough
2 symptoms.

3 The experiments that are Exhibit D reference compared using
4 this Carling's inhaler actually for maintenance therapy with the patients
5 given a second inhaler that had a totally different drug in it, a short-acting
6 bronchodilator for their emergency symptoms, and then comparing that to a
7 patient who is given the same Carling's inhaler but told to begin the
8 instruction to take it for maintenance dose and also as often as needed.

9 And it turned out the patient would take it on average no more
10 than one extra time a day, in addition to the maintenance dose, had far better
11 results in terms of controlling asthma than the patient taking the maintenance
12 dose plus the short-acting inhaler.

13 So the extra treatment with Budesonide gives a benefit in
14 reducing the exacerbations of the serious asthma attacks that wasn't
15 expected.

16 There is an editorial that was published with that article that's
17 Exhibit E here, saying this is a new paradigm in treatment to use Budesonide
18 as an on-demand, the combination of Budesonide and formoterol on
19 demand. New paradigm, they use the words surprising results, remarkable,
20 and so that's what I'd like to say about it.

21 And the examiner has simply ignored that, and we've brought
22 that to her attention and she just says no, Carling teaches it and gives the
23 motivation, and it's just ignoring both our teaching away and our surprising
24 results.

1 JUDGE ADAMS: Ready to shift over? I think the idea there,
2 the examiner is taking the position you don't teach absolute 100 percent
3 prevention of asthma. Your argument is that's not what we're claiming.

4 Your claim is in relation to walking into a smoking
5 environment or exercise and we want to prevent something. When you start
6 noticing, you'll experience an asthmatic attack, we want to prevent that, not
7 fewer asthma attacks.

8 MS. FRASER: Exactly. You did that very well.

9 JUDGE ADAMS: Okay. Thank you.

10 MS. FRASER: Thank you.

11 (Whereupon, the proceedings at 11:51 a.m. were concluded.)